REMARKS

Claims 39 and 61-83 are pending in the present application. By virtue of this response, claims 39 and 61-83 have been cancelled, claims 84-104 have been added. Support for added claims can be found throughout the specification, for example, at [0010]-[0032], [0119]-[0139], [0191]-[0217] and in previously presented claims 61, 68-71, and 74-83. After entry of this response, claims 84-104 are currently under consideration.

Amendment and/or cancellation of the claims listed above are not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Moreover, it is not to be construed that Applicant has acquiesced to any rejections made by the Patent Office. Applicant expressly reserves the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Priority Claim

The specification and application data sheet (ADS) has been amended to reflect that the priority claim for the newly present claims is been amended to claim priority to U.S. Provisional Application No. 60/478,128, filed June 11, 2003.

An updated filing receipt is respectfully requested.

Claim Rejections - 35 USC § 102

Claims 39 and 61-83 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO01/41813.

For the sole purpose of expediting prosecution and without acquiescence, Applicants have canceled claims 39 and 61-83, thus rendering the rejection with respect to these claims moot. Applicants present the following remarks to address any concerns that the Examiner may have with

respect to the newly presented claims. Applicants submit that the newly presented claims are not anticipated by WO01/41813 for the following reasons.

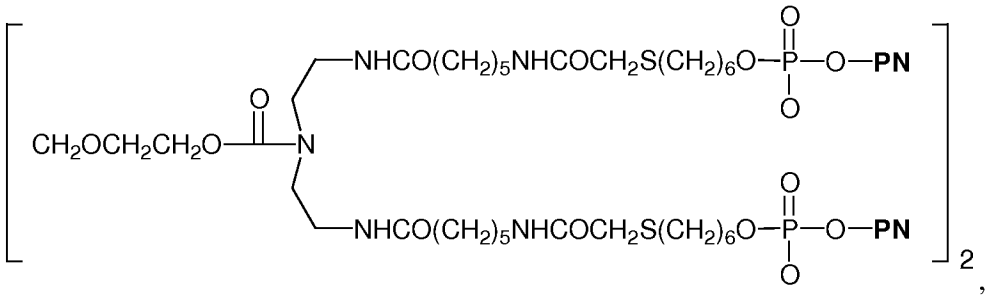
A. The 102(b) reference does not teach every element of the claims and, therefore, does not anticipate the claims.

MPEP 2131 states that to anticipate a claim under 35 U.S.C. 102(b), the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Newly presented claim 84 recites a method of stabilizing or improving the health-related quality of life in a human individual with systemic lupus erythematosus (SLE), comprising the steps of: (a) administering to the individual a composition comprising a dsDNA epitope which specifically binds to an anti-dsDNA antibody; (b) assessing level of circulating anti-ds-DNA antibodies in the individual; (c) identifying the individual as suitable for continued treatment for stabilizing or improving the health-related quality of life if the level of sustained reduction of anti-ds-DNA antibody level is at least about 10% for at least about one month; and (d) continuing to treat the individual only if the individual has the sustained reduction of antibody level.

WO01/41813 does not teach or suggest methods of stabilizing or improving the health-related quality of life in a human individual with systemic lupus erythematosus. WO01/41813 also does not teach or even suggest identifying the individual to whom a composition comprising a dsDNA epitope has been administered as being suitable for continued treatment for stabilizing or improving the health-related quality of life if the level of sustained reduction of anti-ds-DNA antibody level is at least about 10% for at least about one month. Furthermore, WO01/41813 does not teach or even suggest the step of continuing to treat the individual only if the individual has the sustained reduction of antibody level. Thus, WO01/41813 fails to recite each and every element of the claim 84 and therefore does not anticipate claim 84 (and its dependent claims).

Newly presented claim 99 recites a method of stabilizing or improving the health-related quality of life of a human individual with SLE comprising the steps of: (a) administering to the individual an amount of a dsDNA epitope effective to stabilize or improve the health-related quality of life of the individual, wherein administration of the dsDNA epitope results in a sustained reduction in the level of circulating anti-dsDNA antibodies in the individual of at least 10% that is maintained for at least about one month, and wherein the dsDNA epitope is administered in the form of a conjugate of the formula



wherein PN is $(CA)_{10}$•$(TG)_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1));

(b) assessing level of circulating anti-ds-DNA antibodies in the individual; (c) identifying the individual as suitable for continued treatment for stabilizing or improving the health-related quality of life if the level of sustained reduction of anti-ds-DNA antibody level is at least about 10% for at least about one month; and (d) continuing to treat the individual only if the individual has the sustained reduction of antibody level.

As discussed above, WO01/41813 does not teach methods of stabilizing or improving the health-related quality of life in a human individual with systemic lupus erythematosus. It also does not teach that the administration of the dsDNA epitope results in a sustained reduction in the level of circulating anti-dsDNA antibodies in the individual of at least 10% that is maintained for at least about one month, and wherein the dsDNA epitope is administered in the form of a conjugate of the formula indicated above. Furthermore, it does not teach identifying the individual as suitable for continued treatment for stabilizing or improving the health-related quality of life if the level of sustained reduction of anti-ds-DNA antibody level is at least about 10% for at least about one month. Finally, WO01/41813 does not teach the step of continuing to treat the individual only if the

individual has the sustained reduction of antibody level. Thus, WO01/41813 fails to recite each and every element of the claim 99 and therefore, does not anticipate claim 99 (and its dependent claims).

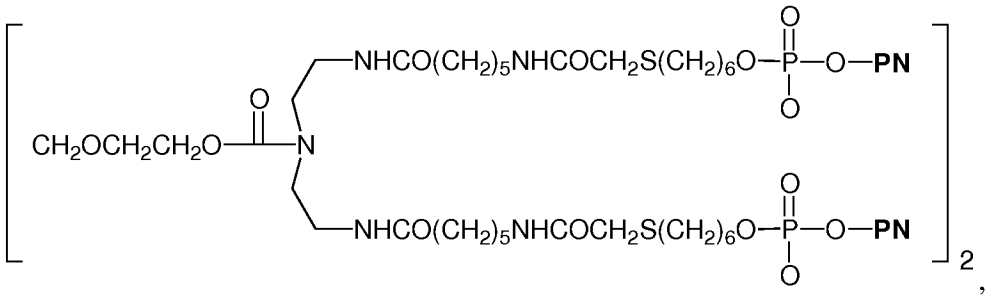
B. WO01/41813 does not teach the limitations arranged or combined in the same way as recited in the claim and, therefore, cannot anticipate the claims.

Currently pending claims 84-104 recite steps that are arranged in a particular order. As stated above, Applicants submit that WO01/41813 does not teach the requisite elements as recited in the claims. However, assuming *arguendo* that the requisite elements were somehow found in the four corners of WO01/41813, this reference would still not meet the standard set forth by the Court of Appeals for the Federal Circuit for anticipation.

In *Net MoneyIN, Inc., v. Verisign, Inc.*, 88 USPQ2d 1751, 1759 (Fed. Cir. 2008), the Federal Circuit held that "unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under *35 U.S.C. § 102*."

WO01/41813 does not teach all the limitations of the claims that are arranged or combined in the same order as the claims. Claims 84 recites a method of stabilizing or improving the health-related quality of life in a human individual with systemic lupus erythematosus (SLE) that comprises four steps. The first is to administer to the individual a composition comprising a dsDNA epitope which specifically binds to an anti-dsDNA antibody. Next, the level of circulating anti-ds-DNA antibodies in the individual is assessed. Then, the next step is to identify the individual as being suitable for continued treatment for stabilizing or improving the health-related quality of life if the level of sustained reduction of anti-ds-DNA antibody level is at least about 10% for at least about one month. Finally, the last step is to continue to treat the individual only if the individual has the sustained reduction of antibody level. WO01/41813 does not disclose these four steps as arranged in the particular order or combination recited in claim 84. Accordingly, applying the standard set forth in *Net MoneyIN*, the WO01/41813 reference fails to anticipate claim 84 (and its dependent claims).

Similarly, claim 99 recites a method of stabilizing or improving the health-related quality of life of a human individual with SLE that comprises four steps. The first step is to administer to the individual an amount of a dsDNA epitope effective to stabilize or improve the health-related quality of life of the individual, wherein administration of the dsDNA epitope results in a sustained reduction in the level of circulating anti-dsDNA antibodies in the individual of at least 10% that is maintained for at least about one month, and wherein the dsDNA epitope is administered in the form of a conjugate of the formula



wherein PN is $(CA)_{10}$•$(TG)_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1)). The second step is to assess the level of circulating anti-ds-DNA antibodies in the individual. The next step is to identifying the individual as being suitable for continued treatment for stabilizing or improving the health-related quality of life if the level of sustained reduction of anti-ds-DNA antibody level is at least about 10% for at least about one month. The final step recited in the claim is to continue to treat the individual only if the individual has the sustained reduction of antibody level. As with claim 84, the steps recited in claim 99 are arranged or combined in a specific way that is not taught in WO01/41813. Therefore, WO01/41813 reference fails to anticipate claim 99 (and its dependent claims).

In view of the foregoing, Applicants submit that claims 84-104 are novel in view of WO01/41813 and respectfully request that the Examiner withdraw this rejection.

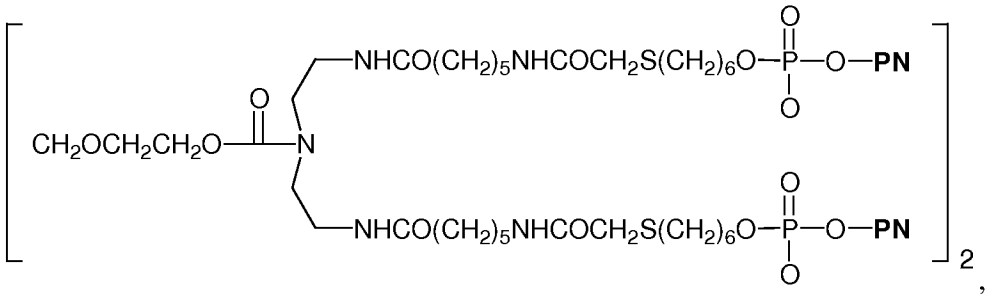
Double Patenting

A. Claims 39 and 61-83 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1-64 of U.S. Patent No. 7,081,242.

Applicants respectfully disagree with the Examiner on this point. However, in the interest of expediting prosecution, Applicants have canceled claims 39 and 61-83 without acquiescing to this allegation. Therefore, with respect to claims 39 and 61-83, this rejection has been rendered moot.

With respect to newly presented claims 84-104, Applicants submit that they are patentable over claims 1-64 of U.S. Patent No. 7,081,242 (the "'242 patent"). The '242 patent does not claim a method of stabilizing or improving the health-related quality of life in a human individual with systemic lupus erythematosus (SLE), comprising the steps of: (a) administering to the individual a composition comprising a dsDNA epitope which specifically binds to an anti-dsDNA antibody; (b) assessing level of circulating anti-ds-DNA antibodies in the individual; (c) identifying the individual as suitable for continued treatment for stabilizing or improving the health-related quality of life if the level of sustained reduction of anti-ds-DNA antibody level is at least about 10% for at least about one month; and (d) continuing to treat the individual only if the individual has the sustained reduction of antibody level. Therefore, claim 84 and its dependent claims are patentably distinct over the claims in the '242 patent.

In addition, the '242 patent does not claim a method of stabilizing or improving the health-related quality of life of a human individual with SLE comprising the steps of: (a) administering to the individual an amount of a dsDNA epitope effective to stabilize or improve the health-related quality of life of the individual, wherein administration of the dsDNA epitope results in a sustained reduction in the level of circulating anti-dsDNA antibodies in the individual of at least 10% that is maintained for at least about one month, and wherein the dsDNA epitope is administered in the form of a conjugate of the formula



wherein PN is $(CA)_{10}$•$(TG)_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1));

(b) assessing level of circulating anti-ds-DNA antibodies in the individual; (c) identifying the individual as suitable for continued treatment for stabilizing or improving the health-related quality of life if the level of sustained reduction of anti-ds-DNA antibody level is at least about 10% for at least about one month; and (d) continuing to treat the individual only if the individual has the sustained reduction of antibody level. Therefore, claim 99 is patentably distinct over the claims in the '242 patent.

B. Claims 39 and 61-83 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1-26 of U.S. Patent Application No. 10/814,555.

Applicants respectfully request that the Examiner hold this rejection in abeyance until such time when the subject matter of the present claims has been deemed to be allowable.

C. Claims 39 and 61-83 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1-39 of U.S. Patent Application No. 11/081,309.

Applicants respectfully request that the Examiner hold this rejection in abeyance until such time when the subject matter of the present claims has been deemed to be allowable.

D. Claims 39 and 61-83 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1-27 of U.S. Patent Application No. 11/347,426.

Applicants respectfully request that the Examiner hold this rejection in abeyance until such time when the subject matter of the present claims has been deemed to be allowable.

E. Claims 39 and 61-83 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1-21 and 34-55 of U.S. Patent Application No. 11/373,699.

Applicants respectfully request that the Examiner hold this rejection in abeyance until such time when the subject matter of the present claims has been deemed to be allowable.

F. Claims 39 and 61-83 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1-26 of U.S. Patent Application No. 11/565,467.

Applicants respectfully request that the Examiner hold this rejection in abeyance until such time when the subject matter of the present claims has been deemed to be allowable.

G. Claims 39 and 61-83 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1-39 of U.S. Patent Application No. 11/562,174.

Applicants respectfully request that the Examiner hold this rejection in abeyance until such time when the subject matter of the present claims has been deemed to be allowable.

Claim Rejections - 35 USC § 112, first paragraph

Claims 72 and 73 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

For the sole purpose of advancing prosecution and without acquiescence to the Examiner's rejection, Applicants have canceled claims 72 and 73, thus rendering this rejection moot. Accordingly, Applicants respectfully request that the Examiner withdraw this rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 252312007900. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: December 16, 2008

Respectfully submitted,

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